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| 10/771,736      | 02/04/2004  | David Knaack         | 2004367-0034        | 5581             |

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BOSTON, MA 02110

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| EXAMINER |
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JAGOE, DONNA A

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| ART UNIT | PAPER NUMBER |
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1619

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11/23/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| <b>Office Action Summary</b> | <b>Application No.</b><br>10/771,736 | <b>Applicant(s)</b><br>KNAACK ET AL. |  |
|                              | <b>Examiner</b><br>Donna Jagoe       | <b>Art Unit</b><br>1619              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-31 and 112-118 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-31 and 112-118 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/22/10</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

***Claims 1-5, 7-31 and 112-118 are pending in this application.***

***Claims 1-5, 7-31 and 112-118 are examined on the merits.***

***Claims 1-5, 7-31 and 112-118 are rejected.***

Applicants' arguments filed July 22, 2010 have been fully considered and they are deemed to be persuasive regarding previous rejections of record. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

However, upon reconsideration, the following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-5, 7-31 and 112-118 have been considered but are moot in view of the new ground(s) of rejection. The Examiner is in agreement with the persuasive remarks submitted concerning previously withdrawn claims 113-118. The claims are examined herein.

### ***Claim Objections***

Claim 118 is objected to because of the following informalities: the word phospholipid in line 3 of the claim is misspelled. Appropriate correction is required.

***Information Disclosure Statement***

The information disclosure statement filed on July 22, 2010 has been reviewed and considered with the exception of those references submitted without a date. See enclosed copy of PTO FORM 1449.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 113 and 115-118 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “modified form of the above” in claim 2, referencing the reinforcement material, is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a reasonable standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Since no guidance is provided as to how “unmodified” these materials can be and still fall within the scope of the instantly claimed subject matter as circumscribed by the term “modified form” the metes and bounds of the term are not clear, making it impossible to ascertain with reasonable precision when that term is infringed and when it is not.

The term “modified form of the phospholipid” in claim 113 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a reasonable standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Since no guidance is provided as to how “unmodified” a phospholipid biomolecule can be and still fall within the scope of the instantly claimed subject matter as circumscribed by the term “modified phospholipid” the metes and bounds of the term are not clear, making it impossible to ascertain with reasonable precision when that term is infringed and when it is not.

The term “modified form of the cholesterol” in claim 115 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a reasonable standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Since no guidance is provided as to how “unmodified” a cholesterol biomolecule can be and still fall within the scope of the instantly claimed subject matter as circumscribed by the term “modified cholesterol” the metes and bounds of the term are not clear, making it impossible to ascertain with reasonable precision when that term is infringed and when it is not.

The term “modified form of the polysaccharide” in claim 116 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a reasonable standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the

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invention. Since no guidance is provided as to how “unmodified” a polysaccharide biomolecule can be and still fall within the scope of the instantly claimed subject matter as circumscribed by the term “modified polysaccharide” the metes and bounds of the term are not clear, making it impossible to ascertain with reasonable precision when that term is infringed and when it is not.

The term “modified form of the starch” in claim 117 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a reasonable standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Since no guidance is provided as to how “unmodified” a starch biomolecule can be and still fall within the scope of the instantly claimed subject matter as circumscribed by the term “modified starch” the metes and bounds of the term are not clear, making it impossible to ascertain with reasonable precision when that term is infringed and when it is not.

The term “modified form of the phospholipid”, “modified form of the cholesterol”, “modified form of the polysaccharide” and “modified form of the starch” in claim 118 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a reasonable standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Since no guidance is provided as to how “unmodified” a phospholipid, cholesterol, starch or polysaccharide biomolecule can be and still fall within the scope of the instantly claimed subject matter as circumscribed by the term

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"modified polysaccharide" the metes and bounds of the term are not clear, making it impossible to ascertain with reasonable precision when that term is infringed and when it is not.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5, 9, 10, 15-31 and 112-113, 115-118 are rejected under 35 U.S.C. 102(a) as being anticipated by Zhang et al. (Tissue Engineering, from IDS dated 11/13/06).

A statement by an applicant in the specification identifying the work of another as "prior art" is an admission which can be relied upon for both anticipation and obviousness determinations, regardless of whether the admitted prior art would otherwise qualify as prior art under the statutory categories of 35 U.S.C. 102. *Riverwood Int'l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1354, 66 USPQ2d 1331, 1337 (Fed. Cir. 2003); *Constant v. Advanced Micro-Devices Inc.*, 848 F.2d 1560, 1570, 7 USPQ2d 1057, 1063 (Fed. Cir. 1988). Where the specification identifies work done by another as "prior art," the subject matter so identified is treated as admitted prior art. *In re Nomiya*, 509 F.2d 566, 571, 184 USPQ 607, 611 (CCPA 1975) (holding applicant's labeling of

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two figures in the application drawings as "prior art" to be an admission that what was pictured was prior art relative to applicant's improvement).

Applicants state that Zhang et al. have synthesized a lysine diisocyanate ethyl ester which they found to be biocompatible, and Applicants' admit that polyurethanes made from this diisocyanate or any other polyisocyanate that are degradable by the host and does not have undesirable toxic effects in vivo may be used to prepare the polyurethanes and composites of the invention (see pages 18 and 19 of the instant specification).

Zhang et al. teach a biodegradable scaffold (matrix) comprising polyurethane (page 1143, column 1 last paragraph) synthesized from lysine diisocyanate (LDI) glycerol (a polyol) and polyethylene glycol (a polyol). Polyols are polymers of sugar which is a term that applicant defines as interchangeable with the term "starch" e.g. see pages 8-9 of the instant specification wherein applicant defines "polysaccharide" "carbohydrate" "oligosaccharide" or "starch" as a polymer of sugars and the terms polysaccharide and carbohydrate may be used interchangeably to mean sugar polymer of any length". Thus the polyols, glycerol and polyethylene glycol, combined with lysine diisocyanate and further comprising biomaterials such as hydroxyapatite (the bone substitute material) and growth factors (Page 1156, column 2) anticipates the claimed invention. Regarding the wet compressive strength, creep rate, fatigue cycles when wet, and degradation rate, as noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald* (205 USPQ 594 (CCPA 1980)), the mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claims



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drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same. Since applicant admits that polyurethanes made from Zhangs' diisocyanate may be used to prepare the polyurethanes and composites of the invention (see pages 18 and 19 of the instant specification), then the properties of the polyurethanes in Zhang et al. would be an inherent characteristic.

Claims 1 and 7 are rejected under 35 U.S.C. 102(a) as being anticipated by Gorna et al. (Journal of Biomedical Materials Research Part A, Oct. 17, 2003) (U).

Gorna et al. teach a biodegradable polyurethane foam for bone graft substitutes (see title) synthesized by reacting hexamethylene diisocyanate, poly(ethylene oxide) diol and poly( $\epsilon$ -caprolactone), an amine based polyol (see abstract). As stated supra, a polyol is a sugar polymer and anticipates the instant invention. Lecithin is added as a surfactant and the composition further comprises calcium carbonate (bone substitute) (see abstract). Gorna et al. teach that using lecithin as surfactant enhanced the miscibility of the reactants with water and consequently led to a foam with a finer and more regular pore structure (page 816, column 2). Lecithin used in synthesis of the polyurethane reduced foam density by 25-35% as compared with the same materials

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which did not contain the organic additives and as it might be expected, the higher the pore:volume ratio, the lower the density of the polyurethane foams (page 816, column 2, para. 2). Gorna further teach that the (polyurethane) foams of citric acid, lecithin or vitamin D3 reduced the mechanical properties, while the presence of inorganic fillers increased the compressive strength and modulus( page 817, column 1).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 8 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorna et al. (U).

Gorna et al. teach a biodegradable polyurethane foam for bone graft substitutes (see title) synthesized by reacting hexamethylene diisocyanate, poly(ethylene oxide) diol and poly( $\epsilon$ -caprolactone), an amine based polyol and the composition further comprises calcium carbonate, and hydroxyapatite as fillers (defined as bone substitutes in the instant claims) (see abstract). As stated supra, a polyol is a sugar polymer and anticipates the instant invention. Gorna et al. further teach that the presence of inorganic fillers, such as the calcium carbonate and hydroxyapatite, increased the compressive strength and modulus (page 817, column 1) and inhibited degradation (page 818, column 1). Since Gorna et al. teach that the calcium carbonate increased the compressive strength of the polyurethane foam one would have been motivated to increase the amount of filler (reinforcement) as required for greater compressive strength.

Claims 1, 2, 4, 5, 9-31 and 112-118 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Boyce et al. (U.S. Patent No. 6,696,073).

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The Boyce et al. reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Boyce et al. teach osteoimplants comprising bone particles combined with binders, bioactive agents, etc (column 10, lines 35-45) wherein suitable binders include polyurethane (column 11, line 18) and the matrix is a bioresorbable polymer (column 26, line 65 to column 27, line 2). Boyce et al further teaches suitable chemical crosslinking agents include hexamethylene diisocyanate and sugars, including glucose (column 16, lines 4-17). Sugar is synonymous with polysaccharide of the claims. Boyce et al. further teach polycaprolactone (column 11, line 2, column 27, example 14). Regarding the percent reinforcement, Boyce et al. teach that the osteoimplant features a reinforcement

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component in a mesh or a structural reinforcement member and a load-bearing osteoimplant reinforcement (see figures 15-17) and teach that the wet compressive strength is from about 10 to about 200 MPa and the differential in compressive strength osteogenicity and other properties between partially and/or fully demineralized bone particles on the one hand and non-demineralized bone particles on the other hand can be concentrated in the region of the osteoimplant that will be directly subjected to applied load upon implantation (column 9, lines 38-63). Regarding the polyurethane that does not fail when subjected to at least  $10^5$  fatigue cycles at 3 MPa when wet or  $10^6$  fatigue cycles at 25 MPa when wet, Boyce et al. teach that when the implant is incorporated and replaced by living host bone tissue, the body can recognize and repair damage, thus eliminating fatigue by fatigue (column 1, line 66 to column 2, line 2). Regarding the "creep rate" and "fatigue cycles" and degradation rate, as noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald* (205 USPQ 594 (CCPA 1980)), the mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same. Regarding the polyurethane that degrades at a sufficient rate to permit generation of

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new tissue at an in vivo implantation site, Boyce et al. teach that the reinforcing component is preferably bioresorbable in order to facilitate the remodeling process (column 13, lines 30-32). Boyce et al. further teach permeation enhancers, such as fatty acid esters, such as laureate, myristate and stearate monoesters of polyethylene glycol (column 13, lines 5-8).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

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double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 7-31 and 112-118 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 86-102 of copending Application No. 11/336127. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant and conflicting claims recite substantially the same subject matter, differing only in the description of the particular components claimed. For instance, conflicting claim 86 requires the composition comprising a polyurethane polymer matrix formed by the reaction of a polyisocyanate with one or more polyol and with embedded particles, such as bone substitute material. Conflicting claims 87 and 88 further define the polyol as a biomolecule and the biomolecule is selected from phospholipids, fatty acids, cholesterol, polysaccharides, lecithin, starches, collagen and combinations. Instant claims 1-5, 7-31 and 112-118 are broadly inclusive thereof because they include reinforcement in the polyurethane matrix, such as calcium carbonate, which is an inorganic material. It would have been obvious to anyone of ordinary skill in the art that the claims overlapped in scope in this manner. One skilled in the art would have been motivated to have interpreted the claims as broadly as is reasonable, and in doing so

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recognize that they are coextensive in scope and thus the proper subject of an obviousness-type double patenting rejection as outlined by *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 2, 4, 5, 8-31 and 112-118 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,696,073. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant and conflicting claims recite substantially the same subject matter, differing only in the description of the particular components claimed. For instance, conflicting claim 7 requires a load-bearing osteoimplant with wet compressive strength of at least about 3 MPa, comprising polyurethane, and reinforcing material. Instant claims 1-5, 7-31 and 112-118 are broadly inclusive thereof because they include a polyurethane matrix with reinforcement such as bone or bone substitutes. It would have been obvious to anyone of ordinary skill in the art that the claims overlapped in scope in this manner. One skilled in the art would have been motivated to have interpreted the claims as broadly as is reasonable, and in doing so recognize that they are coextensive in scope and thus the proper subject of an obviousness-type double patenting rejection as outlined by *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).



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A reference is good not only for what it teaches by the direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re Opprecht* 12 USPQ2d 1235, 1236 (Fed. Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982). In light of the foregoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. § 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was anticipated/prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/YVONNE L. EYLER/  
Supervisory Patent Examiner, Art Unit 1619

Donna Jagoe /D. J./  
Examiner  
Art Unit 1619

October 15, 2010